



DIABETES MELLITUS AND ITS COMPLICATIONS

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DIABETES MELLITUS

Moseby's Medical Dictionary describes Diabetes as "a complex disorder of carbohydrate, fat, and protein metabolism that is primarily the result of a relative or complete lack of insulin secretion by the beta cells of the pancreas or of defects of the insulin receptors." Normally, your body converts carbohydrates, fat, and protein into glucose. The glucose is then carried to the body's cells by the blood stream. Insulin helps the glucose enter the cells where it is metabolized into energy and used, or stored for later use. The systemic defects involving insulin result in an above normal glucose level in the blood stream. Diabetes may effect the eyes, kidneys, nervous system, skin, and circulatory system. Infections are common and atherosclerosis often develops.¹

There are two types of Diabetes Mellitus. Type I Diabetes is characterized by an absolute deficiency of insulin due to a breakdown in production by the pancreas. Type I Diabetes is also called Insulin-Dependent Diabetes and is predominantly hereditary. It most commonly develops in people younger than 20 years old and persists throughout life. Type I Diabetics require insulin injections to prevent Ketosis.²

Type II Diabetes is much more common, representing the majority of all cases. Type II Diabetics have normal, or even above normal, insulin levels. However, the body cannot properly utilize the insulin to allow the glucose to enter the cells. Diet, exercise, and/or anti-diabetic medication can usually control the high glucose levels in the blood stream. For this reason Type II Diabetes is also commonly referred to as Non-Insulin-Dependent Diabetes.³

Type II Diabetes is not predominantly hereditary like Type I. The following is a list of the higher risk groups:

- People who are overweight
- People who are over 40 years of age
- People with a family history of Diabetes
- African-Americans
- Native Americans
- Hispanics

WHAT CAUSES PLANTAR ULCERS?

Diabetics suffer from a loss of normal sensation in their feet, resulting all too often in lesions, or ulcers, that may take weeks, even months, to heal. If not attended to properly the ulcer may become infected, resulting in gangrene and possibly amputation. Ulcerations are the result of pressures and/or repetitive stresses on the foot due to a variety of things like poorly fitted shoes, foot deformities, or foreign objects in the shoe.⁴

The Wagner Scale is most commonly used to grade ulcerations:⁵

Grade 0: No open lesions; may have deformity or cellulitis

Grade 1: Superficial ulcer

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EXHIBIT "A"

- Grade 2: Deep ulcer to tendon, capsule, or bone
- Grade 3: Deep ulcer with abscess, osteomyelitis, or joint sepsis
- Grade 4: Localized gangrene—forefoot or heel
- Grade 5: Gangrene of entire foot

There are three main side effects of Diabetes that cause foot complications: vascular (arterial) disease, peripheral neuropathy (nerve damage), and mechanical alterations of the foot.⁶

The first, vascular disease, causes or aggravates approximately 20 percent of all diabetic foot ulcers. When blood circulation is impaired, the tissues of the foot lose their ability to fight infection and may prevent an ulcer from healing properly.⁷ In addition, poor blood circulation may be a factor contributing to nerve damage.⁸

The second, peripheral neuropathy, is a major contributor to more than 80 percent of all foot ulcers. Numbness, burning, tingling, weakness, and autonomic nervous system changes such as decreased sweating characterize neuropathy. Approximately half of those with long term Diabetes (20 years or more) suffer from significant nerve damage. The nerve damage develops gradually and can go undetected if not carefully monitored by a foot specialist.⁹

The third side effect that contributes to foot problems is mechanical alteration of the foot, caused by variations in nerve damage and limitation of joint motion. Some nerves may be more affected by poor circulation than others, resulting in muscle imbalances. Deformities can develop such as claw or hammer toes, and bony prominences.¹⁰ These deformities, in combination with badly fitted shoes, poor circulation, and weakened skin tissue can result in ulcerations.

Finally, the last contributing factor to foot problems is patient compliance. Patients grow weary of diet, exercise and other lifestyle restrictions and may backslide. Patients that drink alcohol excessively or are obese are typically high at risk. Ill fitting shoes and long hours on the feet at work are also typical problem sources. In some cases a non-compliant diabetic may discover an ulcer and not bring it to the physician's attention. Finally, a non-compliant diabetic will sometimes refuse to wear their prescribed footwear needed to heal the ulcer.

PLANTAR FORCES AND PRESSURE RELIEF

Relieving the pressures and stresses on the ulceration is an accepted mode of treatment. Due to the lengthy healing time it is not practical for the patient to stay off their feet. Therefore, some method of relieving these forces is required while not inhibiting normal day-to-day activity.

There are two forces that are responsible for causing foot ulcerations: normal force, and shear force. Normal force is the direct result of body weight and acts perpendicular to the plantar surface of the foot. Shear force is a result of the deceleration at heel strike and the acceleration at push off. This force acts parallel to the plantar aspect of the foot and can best be described as the frictional force between the foot and the shoe insole. A chart showing the forces acting on the foot during ambulation can be found at the end of this section.

The most common ulcer sites are the metatarsal heads (met heads) located on the ball of the foot. This is due to a unique combination of both normal and shear forces during "push-off." During push-off the normal force becomes concentrated in the met head area resulting in what is known as "peak pressures." These peak pressures magnify the shear force to the point that skin no longer moves under the rotating met heads. The result is tearing of the fragile skin or damage to the soft tissues between the skin and bone (especially if elasticity has been lost due to previous ulceration.) A diagram showing the common sites of ulcers can be found at the end of this section.

TREATMENT WITH THE DH II

The DH II Pressure Relief shoe should be used in conjunction with a complete treatment regime designed by the physician. In order to allow the ulcer to heal the peak pressures and shear forces need to be reduced or eliminated and a more even pressure distribution needs to be achieved over the plantar aspect of the foot. The DH II and the plantar pad are designed to address all of these factors.

The plantar pad is made of three layers of poron, each of a different durometer. Poron is a closed cell polyurethane foam that has a low compression set, meaning it will withstand repetitive compression and still return to its original state. The thin top layer is soft against the skin while the lower levels are progressively firmer to prevent bottoming out. When weight bearing, the pad conforms to the plantar aspect of the foot. This maximizes the area of weight distribution, thus yielding an excellent distribution of pressure ($\text{Pressure} = \text{Force}/\text{Area}$) as well as reducing peak pressures.

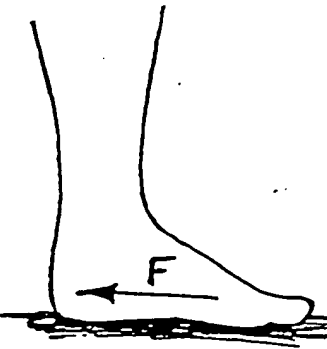
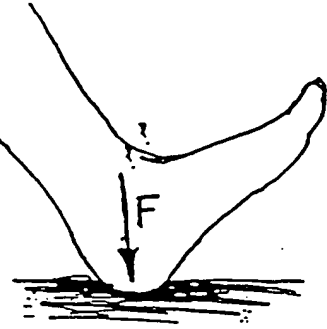
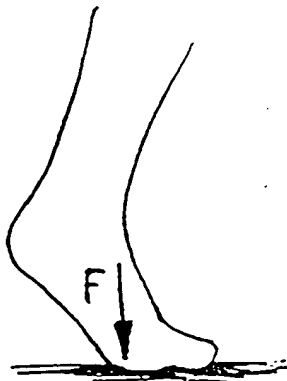


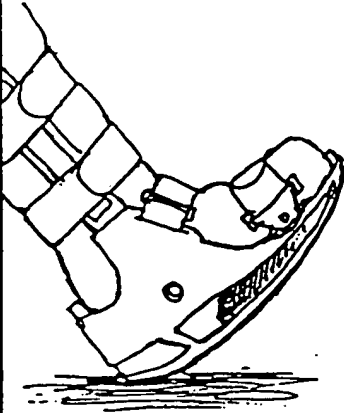
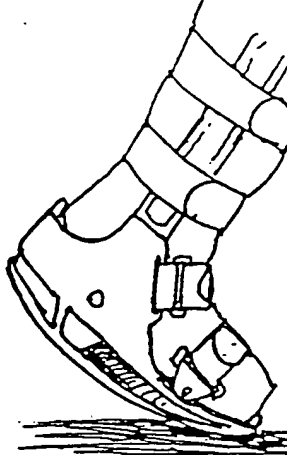
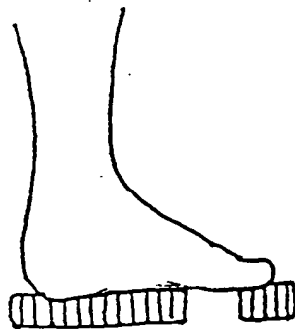
The main feature of the plantar pad is the ability to create pressure relief and shear force reduction with the independently removable hexagons. The area directly underneath the ulceration can be removed thus providing complete pressure relief to the ulcer site. In addition, because the hexagons are all separate entities they are able to move independently when subjected to shear forces, reducing friction and allowing movement of the skin during "push-off."

Another feature that can help offload peak pressures and reduce shear forces is a rocker bottom. Ideally, a totally rigid rocker bottom is used in conjunction with an ankle lock at 90 degrees. The curvature of the sole allows the patient to ambulate while reducing the peak pressures on the met heads during "push-off." However, when the ankle is not locked at 90 degrees, a rigid rocker can actually increase the peak pressures. Because the DH II does not have the ability to lock the ankle at 90 degrees, a semi-rigid rocker sole was utilized. The rocker slope is mild in order to help the stability of the foot.

Finally, the comments most received from customers during the two DH II evaluations was that it is "light weight", "easy to use", and "should improve patient compliance." The DH II can be applied in seconds and weighs approximately 12 ounces. When compared to some of the treatments and competitor products you will see in the next section you will see why they should be more compliant.

FOOTNOTES:

1. Moseby's Medical Dictionary, Fourth Edition, ©1994, Page 469.
2. Moseby's Medical Dictionary, Fourth Edition, ©1994, Page 470.
3. Moseby's Medical Dictionary, Fourth Edition, ©1994, Page 470.
4. "Treatment of Diabetic Foot Ulceration Through Management of Mechanical Forces," by Adam Landsman, DPM, PhD, Podiatric Products, November 1996, Pages 70-71.
5. Medical and Surgical Management of the Diabetic Foot, by Stephen J. Kominsky, ©1994 by Moseby—Year Book, Inc., Page 226.
6. "Feet First," by Nancy N. Bell, Diabetes Forecast, June 1997, Page 28.
7. "Feet First," by Nancy N. Bell, Diabetes Forecast, June 1997, Page 28.
8. The Diabetic Foot, by Marvin E. Levin, Lawrence W. O'neal, and John H. Bowker, ©1993 by Mosby—Year Book, Inc., Page 32.
9. "Feet First," by Nancy N. Bell, Diabetes Forecast, June 1997, Page 28.
10. "Treatment of Diabetic Foot Ulceration Through Management of Mechanical Forces," by Adam Landsman, DPM, PhD, Podiatric Products, November 1996, Page 71.

SHEAR FORCES	NORMAL FORCES	TOE-OFF/PUSH-OFF	PRESSURE RELIEF
			
			
<p>Shear forces are decreased due to the independent shock absorbing hexagons.</p>	<p>The rocker bottom reduces normal and shear forces as well as the gait at toe-off.</p>		<p>Quick and simple removal of the hexagons will provide pressure relief in any plantar aspect area of the foot.</p>

COMMON SITES OF ULCERS

